JAN 0 7 2003

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Acid Phosphatase method for ADVIA® 1650™

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023840

1. Intended Use

The *Bayer ADVIA 1650* Acid Phosphatase assay is an *in vitro* diagnostic device intended to measure total and non-prostatic acid phosphatase concentrations in human serum.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Roche ACP	1553437	759350

3. Device / Method

Product Name	Reagent BAN	Calibrator BAN
Bayer ADVIA® 1650™ Acid Phosphatase	B01-4803-01	B03-4821-01

SUMMARY AND EXPLANATION

Acid phosphatase includes all phosphatases with optimal activity below a pH of 7.0. The greatest concentrations of acid phosphatases are found in human in liver, spleen, milk, erythrocytes, platelets, bone marrow, and prostate gland. Prostatic acid phosphatase is found primarily in the prostate and is tartrate-sensitive. In normal males, prostatic acid phosphatase accounts for about 50% of the serum total acid phosphatase. Enzymatic activity of prostatic acid phosphatase is found elevated in sera of about 60% of men with metastatic prostate cancer. But for carcinomas confined in the prostate gland, the enzyme activity can be normal or only slightly increased. Transient increase in prostatic acid phosphatase can occur after prostate surgery, biopsy, manipulation or catherterization, and in the presence of benign prostate hypertrophy, prostatitis and prostate infarction. Serum total acid phosphatase levels, on the other hand, can be elevated in other diseases and conditions such as Paget's disease, hyperparathyroidism with skeletal involvement, cancer metastases to the bone, Gaucher's disease, Niemann-Pick disease and myelocytic leukemia.

The ADVIA 1650 acid phosphatase method measures total and non-prostatic acid phosphatase in serum by a colorimetric procedure published by Hillmann. Tartrate inhibits prostatic acid phosphatase, allowing for measurement of non-prostatic acid phosphatase. The prostatic acid phosphatase concentration can be manually calculated by determining the difference between total acid phosphatase and non-prostatic acid phosphatase.

Imprecision

TOTAL ACP :

ADVIA 1650		
Level (U/L)	Within Run CV (%)	Total CV(%)
18.39	3.0	9.2
36.98	2.2	4.0
42.23	1.9	3.8

NpACP:

ADVIA 1650		
Level (U/L)	Within Run CV (%)	Total CV(%)
10.01	6.2	9.2
24.50	3.4	4.8
28.88	5.1	7.0

Correlation (Y=ADVIA 1650, X=comparison system)

The performance of this method (Y) was compared to the performance of the Roche Acid Phosphatase method on the Hitachi system (X). The previously marketed device to which the ADVIA 1650 is compared, uses 1,5 pentanediol. This may be the reason for the observed bias between the two (2) devices.

Method	Specimen type	Comparison System (X)	N	Regression Equation	Syx (mg/dL)	R	Sample Range (mg/dL)
NpACP	Serum	Hitachi	64	0.82 x +1.8	2.56	0.987	6.56 to 98.58
Total ACP	Serum	Hitachi	71	0.76 x +0.91	1.95	0.993	4.98 to 106.4

	NpACP	ACP
95% confidence level for slope:	0.787 to 0.856	0.7345-0.7781
95% confidence level for intercept:	0.793 to 2.811	0.189-1.627

Interfering Substances

Interfering Substance	Interfering Sub. Conc. (mg/dL)	ACP Conc (U/L)	Effect (% change)
Bilirubin (unconjugated)	6.25	17.19	-9.3
Bilirubin (conjugated)	6.25	18.42	-1.7
Hemoglobin	50	11.44	-8.8
Lipids (Triglycerides)	1000	17.23	+4.49

Analytical Range

Serum 4 to 200 U/L

Minimum Detectable Concentration

Minimum Detectable Concentration (MDC) was determined from the total standard deviation for water obtained from the Precision study – 11 day, 22 runs, and 44 replicates. The concentration equivalent to Mean+2SD for such samples gave the following MDC: total ACP = 1.98 U/L, npACP = 2.22 U/L.

_____ _____

Andres Holle
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 0 7 2003

Mr. Andres Holle
Regulatory Affairs Manager
Bayer Diagnostics Corporation
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k023840
Trade/Device Name: Acid Phosphatase Assay for the ADVIA® 1650™
Regulation Number: 21 CFR 862.1020
Regulation Name: Acid Phosphatase test system
Regulatory Class: Class II
Product Code: CKB; JIX; JJY
Dated: December 23, 2002
Received: December 24, 2002

Dear Mr. Holle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023840

Device Name: Acid Phosphatase Assay for the ADVIA® 1650™

Indications for Use:
The *Bayer ADVIA 1650* Acid Phosphatase assay is an *in vitro* diagnostic device intended to quantitatively measure total and non-prostatic acid phosphatase concentration in human serum.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K023840

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)